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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/305,984	05/05/99	NOVAK	1340-1-016-N

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DAVID A JACKSON ESQ
KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK NJ 07601

EXAMINER

LEE, L

ART UNIT	PAPER NUMBER
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1645

10

DATE MAILED: 08/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/305,984

Applicant(s)

Novak et al

Examiner

Li Lee

Group Art Unit
1645



☒ Responsive to communication(s) filed on Jan 12, 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-67 is/are pending in the application

Of the above, claim(s) 1-33 and 40-67 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 34-39 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1 This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant's disclosure of amino acid/nucleotide sequences on pages 7, 9, 10, 11, 14, 16, 17, 18, 30, 74, 82, 94 (claim 10), and 94 (claim 20) in the specification must comply with the sequence rules (e.g., a SEQ ID NO is required for each of the sequences).

Election/Restriction

2. Applicant's election with traverse of Group VI, claims 34-39 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the examination of the entire application cannot constitute a serious burden and claims 25-28 of Group IV drawn to methods of identifying a peptide that are fundamentally related to claims 34-39 of Group VI drawn to methods of identifying agents capable of inhibiting growth or killing a bacterial cell because they have the identical classification. These arguments have been fully considered but not found to be persuasive for the reasons below.

MPEP 803 states that restriction is proper between patentable distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

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In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-IX are classified separately necessitating different searches of issued U.S. Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because, for example, search for invention of Group VI, a method of identifying an agent by utilizing a deficient bacterial cell is not co-extensive to a search for invention of Group IV, a method of identifying a peptide that can stimulate the lysis of a wild type bacterial strain. Additionally, it is submitted that the inventions of Groups I-IX have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For reasons set forth in the previous office action and above the restriction requirement is deemed to be proper and is therefore made FINAL.

3. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings are objected to by the draftsman under 37 C.R.F. 1.84 or 1.152. See PTO-948 for details. Correction of the noted defects can be deferred until the application is allowed by the examiner.

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4. Items listed on form PTO-1449 filed on Apr 03, 2000 have be considered by the examiner.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 34-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Williamson et al (J Bacteriology 114 (1): 105-13, 1980).

Williamson et al teach a method of identifying an agent (e.g., an antibiotic) that is capable of inhibiting the growth of or killing a bacterial cell, comprising contacting the agent/antibiotic with a bacterial cell, the mutant *Streptococcus pneumoniae* cell and determining whether the cell is killed or its growth is inhibited and then the agent/antibiotic is identified as capable of killing or inhibiting the growth of a bacterial cell if it kills or inhibits the growth of the bacterial cell (Abstract). Williamson et al also teach that the mutant *Streptococcus pneumoniae* cell is a vancomycin tolerant cell. The art teach that vancomycin tolerance in mutant *Streptococcus pneumoniae* is due to the lacking of function of the sensor histidine kinase (having a wild type amino acid sequence SEQ ID NO:14) or lacking of function of response regulator (having a wild type amino acid sequence SEQ ID NO:16) (Novak et al Nature 399:590, 1999). Since these

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response regulators are important components of His-Asp phosphorelay signal transduction pathway, lacking the function of response regulator results a defective His-Asp phosphorelay pathway. Williamson et al do not expressly teach if the vancomycin tolerant cell is not killed by a peptide having the amino acid sequence of SEQ ID NO:2 which has a antibiotic activity on a bacterial cell. However, the cell of Williamson et al has identical biological function (e.g., antibiotic tolerance) as the one used in the claimed method, one skilled in the art can conclude that the cell of Williamson et al by necessity will not be killed by the amino acid sequence of SEQ ID NO:2. Since the US Patent Office does not have the facilities for examining and comparing applicants' product with the product of the prior art reference, the burden is on applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Thus, Williamson et al meet the limitations of the claims.

Status of Claims

7. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee
July 31, 2000



PHUONG T. BUI
PRIMARY EXAMINER